

MILAGROSO- methyl salicylate ointment
Pharmadel LLC

Milagroso Methyl Salicylate 10% (WP)(DA)

Drug Facts

Active ingredient & Purpose

<i>Active ingredient</i>	<i>Purpose</i>
Methyl salicylate 10%	External analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For external use only. Avoid contact with the eyes.

Do not

- apply on wounds or irritated skin
- bandage tightly

Stop use and ask doctor immediately if

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

If swallowed get medical help, or contact a Poison Control Center immediately.

Directions

- **adults and children 12 years of age and older:** apply to affected area not more

than 3 to 4 times daily

- **children under 12 years of age:** do not use, consult a doctor

Other information

- store between 59°- 86°F (15 - 30°C)
- do not use if clear seal over jar is broken, torn or missing

Inactive ingredients

camphor, D&C yellow #11, lanolin oil, levomenthol, mineral oil, paraffin, petrolatum, propylparaben

Distributed by:

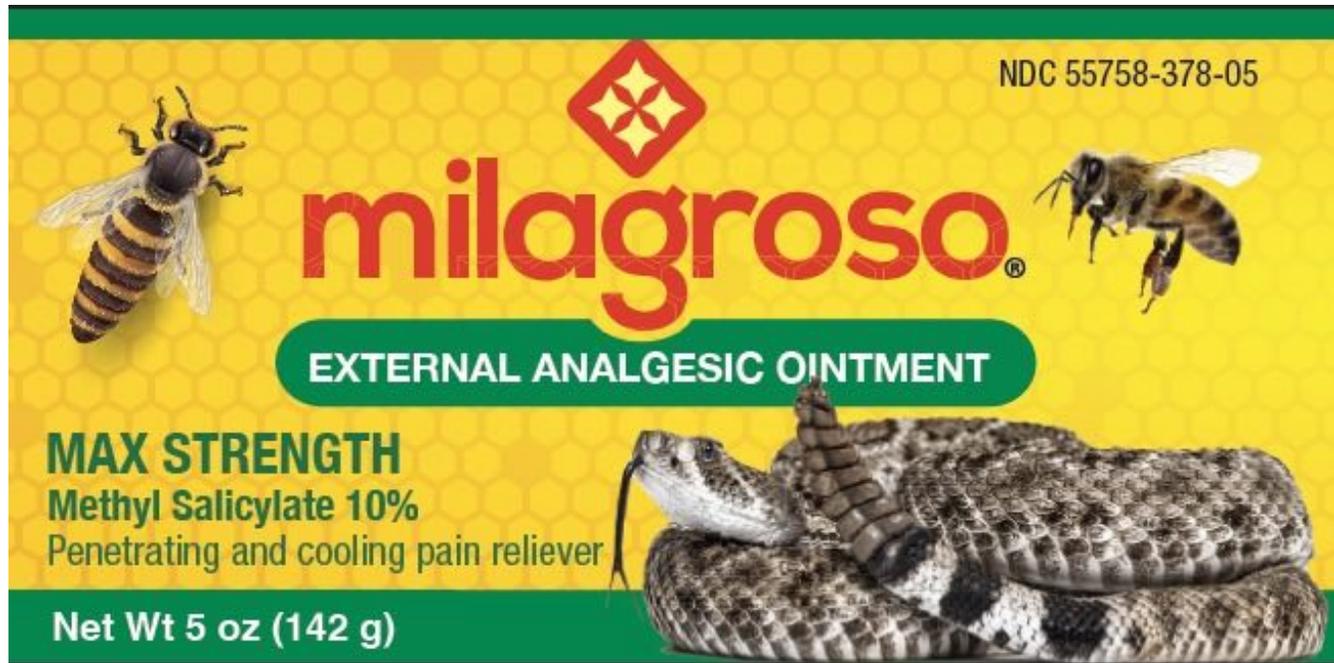
Pharmadel LLC

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Principal Display Panel

Milagroso® does not contain bee venom or snake oil but contains an active ingredient that is used as an effective analgesic.



MILAGROSO

methyl salicylate ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:55758-378

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	CAMPHOR, (-)- (UNII: 213N3S8275)			
	LEVOMENTHOL (UNII: BZ1R15MTK7)			
	D&C YELLOW NO. 11 (UNII: 44F3HYL954)			
	PARAFFIN (UNII: I9O0E3H2ZE)			
	PROPYLPARABEN (UNII: Z8IX2SC1OH)			
	PETROLATUM (UNII: 4T6H12BN9U)			
	LANOLIN OIL (UNII: OVV5IJ58F)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-378-05	142 g in 1 JAR; Type 0: Not a Combination Product	06/10/2023	08/01/2027
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	06/10/2023	08/01/2027	

Labeler - Pharmadel LLC (030129680)

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Pharmadel LLC